Remarks

Reconsideration of this application is respectfully requested.

Claim 55 is sought to be canceled without prejudice or disclaimer of the subject matter contained therein, claims 2, 8, 41, 46 and 56 are sought to be amended, and new claim 57 is sought to be added. Upon entry of the foregoing amendment, claims 2, 4-16, 41-54, 56 and 57 are currently under consideration in the application, with claims 2 and 41 being the independent claims.

Support for the amendments to the claims can be found throughout the specification and in the claims as originally filed. In particular, support for the amendment to claim 2 and new claim 57 can be found, for example, in the specification at page 4, lines 27-28, page 5, lines 3-6, page 6, lines 5-11, and page 20, line 22 to page 21, line 7. Support for the amendment to claim 56 can be found, for example, in the specification at page 5, lines 27-29, page 6, lines 8-11, page 10, lines 7-15, page 18, lines 5-10, page 20, line 20 to page 21, line 17, and page 37, lines 10-14. The amendment of claims 2, 8, 46 and 56 merely make that which was implicit within each claim explicit.

It is believed that this amendment will put the case in condition for allowance or better form for consideration on appeal. In addition, these changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claims 55 and 56 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. (*See* Paper No. 19, page 2.)

Specifically, the Examiner contends that "[t]he claims are drawn to derivatives of a plasmid, 'pAIM56'. However, the metes and bounds of what would be considered a 'derivative' of the plasmid cannot be determined." (Paper No. 19, page 2.) Applicants respectfully traverse this rejection as it may apply to the currently pending claims. T h e definiteness requirement "requires the language of the claim to set forth clearly the domain over which the applicant seeks exclusive rights." *Process Control Corp. v. HydReclaim Corp.*, 52 USPQ2d 1029, 1034 n.2 (Fed. Cir. 1999). Further, "[t]he test for whether a claim meets the definiteness requirement is 'whether one skilled in the art would understand the bounds of the claim when read in light of the specification.'" *Process Control*, 52 USPQ2d at 1034 n.2 (quoting *Personalized Media Communications v. Int'l Trade Comm'n,* 48 USPQ2d 1880, 1888 (Fed. Cir. 1998)). "If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more." *Miles Laboratories, Inc. v. Shandon Inc.,* 997 F.2d 870, 875 (Fed. Cir. 1993), *cert. denied*, 510 U.S. 1100 (1994) (citations omitted).

Applicants note that claim 55 has been canceled, and that claim 56 has been amended to recite that the pAIM65 derivative contains a deletion of nucleotides 36,818 - 37,972 of the wild type CELO virus genome. Applicants submit that claim 56, when read in light of the specification, reasonably apprises one skilled in the art of the metes and bounds of the claimed invention.

With respect to pAIM65 derivatives, the specification discloses that

> CELO virus or CELO virus DNA with Gam1 disruptions, and their derivatives respectively, have been designated CELO AIM65 or CELO AIM65 derivatives, respectively.

(Specification, page 5, lines 27-29.)

The specification further discloses how to generate pAIM65. In particular, in order to produce a recombinant CELO virus genome with a Gam1 disruption,

> a plasmid bearing the genomic right end 13.3 kb fragment is modified to delete a portion of the Gam1 coding sequence and an expression cassette, e.g. a BamHI CMV/luciferase/ßglobin expression cassette is inserted by standard ligation cloning. This modified region is built into a recombinant CELO genome by homologous recombination to produce a plasmid (designated pAIM65).

(Specification, page 10, lines 8-15.) The portion of the Gam1 coding sequence which is deleted is from nucleotide 36,818 to nucleotide 37,972. (*See* Specification, page 20, line 23 to page 21, line 14.) "[T]he CELO virus, e.g. CELO AIM65 or its derivatives, is engineered, as described above, by introducing the cDNA or, preferably, an expression cassette, encoding the protein of interest into one of the insertion sites of the recombinant CELO DNA of the invention." (Specification, page 18, lines 5-10.)

As such, the specification clearly discloses that pAIM65 comprises the CELO virus genome with a deletion from nucleotide 36,818 to nucleotide 37,972 and with a luciferase expression cassette inserted therein. In addition, the specification discloses that derivatives of pAIM65 can contain the same deletion with different insertions and provides an example of such a derivative. (*See* Specification, page 18, lines 5-10 and page 37, lines 10-14.) In view of the above, Applicants assert that the metes and bounds of what would be considered a "derivative" of pAIM65 could easily be determined by those skilled in the art.

The Examiner's grounds of rejection of claims 55 and 56 under 35 U.S.C. § 112, second paragraph, have been addressed by Applicants' amendments and/or remarks. Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection.

Double Patenting

The Examiner rejected claims 2, 4-16 and 41-56 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1, 4, 5, 8, 16, 20-28, 30-34, 81, 83 and 149-162 of U.S. Patent No. 6,335,016 ("the '016 patent"). (*See* Paper No. 19, pages 2-3.) The Examiner indicated that "[t]his rejection will be obviated once a terminal disclaimer is received." (Paper No. 19, page 3.)

Rejections under 35 U.S.C. § 102

The Examiner rejected claims 2, 4, 5, 7, 8, 41-43, 45, 46, 55 and 56 under 35 U.S.C. § 102(a) as allegedly being anticipated by Michou *et al.*, *Journal of Virology 73*:1399-1410 (1999). (*See* Paper No. 19, page 3.) The Examiner also rejected claims 2, 4-16 and 41-56 under 35 U.S.C. § 102(b) as allegedly being anticipated by Baker *et al.*, International Publication No. WO 97/40180 and under 35 U.S.C. § 102(e) as allegedly being anticipated by Baker *et al.*, U.S. Patent No. 6,335,016.[1] (*See* Paper No. 19, page 4.) In particular, it was the Examiner's position that "one of ordinary skill in the art would envisage any specific

[1]Applicants note that U.S. Patent No. 6,335,016 issued from U.S. Application No. 09/171,461, which is the U.S. National Stage application of PCT/EP97/01944, *i.e.*, International Publication No. WO 97/40180. Accordingly, the '016 patent and WO 97/40180 share the same specification, and the discussion of WO 97/40180 is likewise applicable to the '016 patent.

range of nucleic acid deletions taught in the cited references." (Paper No. 19, page 5.) Applicants respectfully traverse this rejection it may apply to the currently pending claims.

Specifically, the Examiner asserted that

> Michou et al. specifically teaches deletion of Gam1 within the deleted range, see figure 3 on page 1403. Therefore, it is apparent that the skilled artisan would be able to immediately envision smaller deletions taught by Michou et al. based on the information provided regarding right end open reading frames.

(Paper No. 19, page 5.)

As indicated by the Examiner, Figure 3 of Michou *et al.* shows plasmid pAIM45 which contains a deletion of nucleotides 33,358 to 43,684 of the CELO virus genome, which encompasses the Gam1 gene open reading frame. What is *not specifically disclosed*, however, is a recombinant CELO virus or CELO virus DNA, characterized in that the region spanning nucleotides 37,391 - 37,972, nucleotides 36,818 - 37,972, and/or nucleotides 37,391 - 38,239 of the CELO wild type virus genome is deleted.

When a claimed compound is not specifically named in a prior art reference, but instead it is necessary to select various substituents from a list of alternatives, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. *See, e.g., Ex parte A*, 17 USPQ2d 1716, 1718 (BPAI 1990). That is, a genus will anticipate a species within that genus which is *not expressly disclosed* if one of ordinary skill would "at once envisage" the claimed compound from the disclosed genus. *See In re Petering*, 133 USPQ 275, 280 (CCPA 1962). It is the Examiner's position that although Michou *et al.* do not expressly disclose the presently claimed deletions, the "genus" of deletions disclosed in Michou *et al.* nevertheless anticipates the "species" of deletions of the present invention because the skilled artisan would be able to "immediately envision smaller deletions."

Applicants acknowledge that "the disclosure of a small genus may anticipate the species of that genus even if the species are not themselves recited." *Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.*, 58 USPQ2d 1508, 1517 (Fed. Cir. 2001) (citing *In re Petering*, 133 USPQ 275, 280 (CCPA 1962)). However, in order for Michou *et al.* to anticipate the claimed invention, the number of possible deletions would need to be so few that the disclosure of Michou *et al.* would have been understood by one of skill in the art as a suggestion to specifically delete regions 37,391 - 37,972, 36,818 - 37,972, and/or 37,391 - 38,239 of the CELO wild type virus genome. *See Bristol-Myers Squibb Co.*, 58 USPQ2d at 1517. Applicants submit that the general class of deletions in Michou *et al.*'s disclosure is not small enough such that the disclosure of deletions effectively describes the specifically claimed deletions for the purposes of section 102.

In *In re Petering,* it was found that even though the prior art did not expressly disclose the claimed compounds, the claims were nevertheless anticipated by the art reference since the reference described a limited class of 20 compounds which included the claimed compounds. *See In re Petering*, 133 USPQ 275 (CCPA 1962). More specifically, the court stated:

> A simple calculation will show that, excluding isomerism within certain of the R groups, the limited class we find in [the prior art] contains only *20 compounds*. . . . [W]e hold that each compound within the limited class in [the prior art] . . . has been described in a printed publication within the meaning of 35 U.S.C. 102(b), and that it is of no moment that each compound is not specifically named or shown by structural formula in that publication.

In re Petering, 133 USPQ at 280 (emphasis added).

Similarly, it was held in *In re Schaumann* that a prior art patent which encompassed a very limited number of compounds, *i.e.*, *seven*[2], that were closely related to one another in structure and encompassed applicant's claimed compound provided a description of the compounds just as if they were explicitly recited by name. *See In re Schaumann*, 197 USPQ 5, 9 (CCPA 1978). In particular, the court indicated:

> [W]e believe the circumstances in the present case provide a far stronger foundation on which to support a finding of anticipation than did the circumstances in Petering. In order to find anticipation in Petering, it was necessary to derive a class of compounds of lesser scope than the genus actually disclosed in the reference on the basis of preferences ascertainable from the remainder of the disclosure, which included eight specific examples of isoalloxazine derivatives. In the present case, by contrast, [the prior art patent's] preference for lower alkyl secondary amines is expressly set forth in claim 1.

In re Schaumann, 197 USPQ at 9.

Applicants note, however, that the rejection of a claimed species in light of a prior art genus is not appropriate where the prior art does not disclose a small recognizable class of compounds with common properties. *See In re Ruschig*, 145 USPQ 274 (CCPA 1965).

In *In re Ruschig,* two generic claims defining limited classes of benzenesulfonylureas were rejected on the basis of the broader generic disclosures of three references which were alleged to have anticipated the claimed subject matter, a U.S. patent, a French patent and a Swedish patent. In reversing the rejection, the court indicated:

> [W]e do not find the present case to be of the type we had before us in Petering. Even if we take the 10 examples of the

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[2]"[T]he examiner noted that the method disclosed by Hildebrandt for producing β-(meta-hydroxyphenyl)-isopropylamines would result only in the production of secondary amines, thus limiting to fourteen the number of possible compounds taught by the reference. That number is further reduced to seven, said the examiner, if one considers the preference for lower alkyl secondary amines expressed in claim 1 of the reference." *In re Schaumann*, 197 USPQ at 9.

> French or the 12 examples of the Swedish reference, take them apart and recombine them into different compounds than those named, we do not get a small recognizable class with common properties. We would apparently get from the French patent some 130 and from the Swedish some 156 compounds. . . . We hold similar views as to the board's indication that a specific *description* of compounds within claims 1 and 2 can be made out of the [U.S. patent] disclosure. To do this the board selects p-chloro- and p-bromo- for R (as used in appellants' claim 2, supra) and ethyl or isoamyl for R_2 to create, ex post facto, four undisclosed specific compounds out of a possible 259, according to appellants' apparently valid calculations. This is not the kind of *description* we found in Petering and we do not find here any "anticipation" by the [U.S.] patent of claims 1 and 2.

In re Ruschig, 145 USPQ at 282 (emphasis in original). As such, the court found that the description of *259, 156 or even 130* compounds by prior art references was not a small recognizable class of compounds such that each compound within the genus was described within the meaning of 35 U.S.C. §102.

According to the Examiner, the skilled artisan would be able to immediately envision smaller deletions taught by Michou *et al.* (*See* Paper No. 19, page 5.) However, the range of nucleotide deletions is over 10,000 nucleotides. The number of possible deletions is well over 7, 20 or even 259. Accordingly, Applicants submit that Michou *et al.* do not disclose a small recognizable class of compounds with common properties such that the skilled artisan, given only the disclosure of Michou *et al.*, could "at once envisage" Applicants' presently claimed compounds.

It is the Examiner's position that one of ordinary skill in the art would envisage any specific range of nucleic acid deletions taught by the Baker *et al.* references as well. (*See* Paper No. 19, page 5.) In particular, it is the Examiner's position that

> [c]ontrary to applicant's assertion that Baker et al.[3] does not anticipate limiting the range of deletions taught, Baker et al. specifically teaches that the virus "contains modifications which are located on a section of CELO virus DNA which comprises the nucleotides . . . from about 31,800 - about 43,734 . . ." . . . . This explicit teaching of the modifications within the regions anticipate any partial deletion of the entire region taught by Baker et al. anticipates [sic] all and every possible deletion therein.

(Paper No. 19, page 5.) Applicants respectfully submit that the explicit teaching by Baker *et al.* that modifications may be located on a section of CELO virus DNA which comprises the nucleotides from about 31,800 - about 43,734 does *not anticipate all and every possible deletion therein.*

Applicants reassert that "although . . . specific claims are subsumed in [a prior art reference's] generalized disclosure . . ., this is not literal identity." *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 24 USPQ2d 1321, 1332 (Fed. Cir. 1992). Furthermore, a genus will anticipate a species within that genus which is *not expressly disclosed* if one of ordinary skill would "at once envisage" the claimed compound from the disclosed genus. *See In re Petering*, 133 USPQ 275, 280 (CCPA 1962). As discussed above, the rejection of a claimed species in light of a prior art genus is not appropriate where the prior art does not disclose a small recognizable class of compounds, *e.g.* seven or twenty, with common properties.

Since the region of Baker *et al.* contains nearly 12,000 nucleotides and any or all of the nucleotides within the region can be deleted and the deletion of different nucleotides generates a recombinant CELO virus with different properties, Applicants submit that one

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[3]Since the disclosures of the Baker *et al.* references are the same, the Examiner indicated that Baker *et al.* '180 was cited to address arguments against both Baker *et al.* references for the purpose of convenience. (*See* Paper No. 19, page 5.)

skilled in the art, given the disclosure of these references, could not "at once envisage" Applicants' presently claimed invention in view of the vast number of possible deletions and the way that standard has been interpreted by the courts.

In view of the fact that the cited references fail to expressly set forth any of Applicants' claimed regions and that one skilled in the art would be unable to immediately envisage Applicants' claimed regions from the disclosed genuses, Applicants submit that the present invention is not anticipated by Michou *et al.*, WO 97/40180 or the '016 patent. Accordingly, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 102 be withdrawn.

With respect to claims 55 and 56, the Examiner indicated that the plasmid of Michou *et al.* encoding the recombinant CELO virus is a pAIM plasmid and therefore anticipates the pAIM65 "derivatives" recited in claim 55 and 56. (*See* Paper No. 19, page 3.) Further regarding claims 55 and 56, it is the Examiner's position that

> [b]oth Baker et al. references anticipate new claims 55 and 56 because a derivative of the instant pAIM65 is presumed to be any plasimd [sic] that expresses a modified CELO virus with disrupted GAM1 expression that replicates in prokaryotic or eukaryotic cells. Both Baker et al. references teach a plasmid encoding a modified CELO virus that lacks the sequences necessary for GAM expression that is replicable in bacteria, yeast, or bird embryo kidney or liver cell lines . . . . Therefore, Baker et al. (WO'180 and US '016) anticipate pAIM65 derivatives.

(Paper No. 19, page 4.)

Applicants note that claim 55 has been canceled and claim 56 has been amended to recite that the pAIM65 derivative contains a deletion of nucleotides 36,818 - 37,972 of the wild type CELO virus genome. In view of the amendment to claim 56 and Applicants' arguments above, Applicants respectfully assert that the Examiner's grounds of rejection of

claims 55 and 56 under 35 U.S.C. § 102 have been addressed. Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Version with Markings to Show Changes Made

In the Claims:

Claim 55 was canceled without prejudice to or disclaimer of the subject matter contained therein.

Pending claims 2, 8, 41, 46 and 56 were substituted with the following claims 2, 8, 41, 46 and 56:

2. (Twice amended) Recombinant CELO virus or CELO virus DNA, characterized in that the region spanning nucleotides 37,391 - 37,972 [37391-38239] of the CELO wild type virus genome is [completely or partially] deleted [or altered and/or contains an insertion], wherein said deletion[, alteration or insertion] results in a complete loss of Gam1 expression or prevents the expression of a functional Gam1 protein.

8. (Twice amended) The recombinant CELO virus or CELO virus DNA of claim 2, characterized in that it contains a foreign DNA insertion within said region [in place of one or more deletions].

41. (Once amended) Recombinant CELO virus or CELO virus DNA, characterized in that the region spanning nucleotides 36,818 - 37,972 [36818-37972] of the wild type CELO virus genome is [completely or partially] deleted [or altered and/or contains an insertion], wherein said deletion[, alteration or insertion] results in a complete loss of Gam1 expression or prevents the expression of a functional Gam1 protein.

46. (Once amended) The recombinant CELO virus or CELO virus DNA of claim 41, characterized in that it contains a foreign DNA insertion within said region [in place of one or more deletions].

56. (Once amended) The recombinant CELO virus DNA of claim 45, wherein said plasmid is pAIM65 or a derivative thereof, wherein said derivative contains a deletion of nucleotides 36,818 - 37,972 of the wild type CELO virus genome.

Claim 57 was added.